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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,431	01/25/2002	Peter Paasch Mortensen	10127.200-US	9691
25908	7590	02/01/2005	EXAMINER	
NOVOZYMES NORTH AMERICA, INC.			DEJONG, ERIC S	
500 FIFTH AVENUE			ART UNIT	
SUITE 1600			PAPER NUMBER	
NEW YORK, NY 10110			1631	

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,431

Applicant(s)

MORTENSEN, PETER PAASCH

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 28 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20, 28, and 44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The communication filed by applicant on 18 November 2004 comprising a response to the previous Office Action and an amended list of claims is acknowledged. The amended list of claims is accepted and replaces all previous claims for the instant application. Claims 1-20, 28, and 44 are pending in the application. Claim 28 is withdrawn from consideration as being drawn to a non-elected invention. Claims 21-27 and 29-43 are canceled. Claims 1-20 and 44 are currently under examination.

Applicants arguments, filed 18 November 2004, have been fully considered and they are not deemed to be persuasive. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants submit that the step of "predicting the amount of fluorescent marker" is not used in the specification and would not be interpreted as

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forecasting into the future, but rather that the term is used to convey that the determination is not a direct measurement of the amount of fluorescent marker and instead this measurement is based on a reliable correlation with the amount of light emitted. Applicants further submit support for this assertion as well as the amendments to claims 1, 10, and 11 for is provided in the instant specification on page 6, lines 12-16.

In claim 1, line 4 the phrase "correlating the amount of fluorescent marker in the granular compositions with the amount of emitted light" still maintains the limitation of the prior version of the claim 1 wherein the phrase "predicting the amount of fluorescent marker" was recited. The instant specification teaches that "to correlate the amount of emitted lights to one or ~~o~~ more properties of the granular composition" is accomplished "by predicting the amount of fluorescent marker in the granular composition accessible to fluorescence excitation". See the instant specification, page 6, lines 13-16. Further, the applicants assertion that the step of "predicting the amount of fluorescent marker" is not used in the instant specification is refuted by the quotation from the instant specification, page 6, line 15.

As taught by the instant specification, for one of skill in the art to perform the third step of correlating the amount of emitted light the limitation of "predicting the amount of fluorescent marker" is necessarily encountered. As such, the basis of the rejection from the previous Office Action is maintained as it is not clear what predicting is meant regarding an illuminated/detected composition. This

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uncertainty also remains present in claims which depend directly or indirectly from claim 1.

Applicants assert that the claims have been amended to remove the objectionable term from claims 1, 10, and 11. (emphasis added)

As a point of clarification, the phrase "predicting the amount of fluorescent marker" was the basis for a **rejection** under the second paragraph of 35 U.S.C. 112 rather than a basis for an **objection** under a Title 37 CFR Patent Rule.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over McNamara et al. (Patent Number 6,007,996).

This rejection is maintained and reiterated from the previous office action, mailed 29 June 2004.

Applicants assert that McNamara et al.'s granular samples, such as Figures 4A, 4B, 5A, 5B, etc., are not "granular compositions" as recited by the instant claims and cites the instant specification page 10, line 29 to page 15, line 17 to clarify what limitations are intended by use of the phrase "granular compositions".

The instant specification teaches "(t)he granular composition of the invention is a composition comprising the biologically active compound, a

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fluorescent marker, which may be the biologically active compound itself and optionally auxiliary granulation agents and coating agents processed into particles or granules." See the instant specification, page 10, line 29 through page 11, line 3. Further the instant specification teaches "(t)he term 'granules' are to be understood as a predominantly spherical or near spherical structure of a macromolecular size." See the instant specification, page 11, lines 5-7. The specification also teaches several examples and preferred embodiments related to the size of the granular compositions recited in the claims, but such examples and preferences do not provide a specific definition or absolute range that strictly limit the particle's size.

Figures 4A, 4B, 5A, and 5B from McNamara et al. provide examples that meet the above described limitations set forth by the instant specification, as each figure represents the detection by fluorescence means biologically active compounds (cells and chromosomes), each compound contains fluorescent markers, and the structures presented are predominantly or nearly spherical.

Applicants further assert that there is no motivation to apply the McNamara et al. cellular analysis process to the analysis of granular composition as recited in the claimed invention.

As described above, the cells and chromosomes observed by fluorescent markers in the examples of Figures 4A, 4B, 5A, and 6B from McNamara et al. meet the limitations established by the instant specification for "granular compositions". As such, the scope of the McNamara et al. cellular analysis

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process clearly encompasses the analysis of granular compositions as recited in the instantly claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-

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0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 2723-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ardin H. Marschel 1/31/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER